K063583

5. 510(K) SUMMARY

This summary is in accordance with 21 CFR 807.92(c).

MAY - 9 2008

The submitter of the 510(k) is:

Terry J. Dagnon
Director, Regulatory Affairs
Alcon, Inc.
6201 South Freeway
Fort Worth, Texas 76134
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Date Prepared: May 8, 2008

Device Subject to this 510(k):

Trade Name:	Alcon Vision System
Common Name:	Vitreous Aspiration & Cutting Instrument
Classification Name:	Class II
	Vitreous Aspiration & Cutting Instrument (21 CFR 886.4150)
	Phacofragmentation System (21 CFR 886.4670)

5.1. Predicate Devices

510(k) Number	Device
K911808	Alcon Accurus® Surgical System (Gemini Ophthalmic Surgery System)
K961310	Storz Premiere® II/Bausch and Lomb Millennium™
K021566	Alcon Infiniti® Vision System
K981116	Allergan Sovereign® Cataract Extraction System
K032598	Synergetics Photon Illuminator

5.2. Device Description

The Alcon Vision System is a combined anterior and posterior procedure ophthalmic system that is modular in design and serves as an enhanced version of the current Alcon Accurus® system. The Alcon Vision System is designed for use in anterior and posterior procedures

that require infusion, vitreous cutting, aspiration, and illumination as well as irrigation, lens emulsification and fragmentation, cautery and diathermy. The system was developed with a dual purpose: to make it simple to operate, and to allow the surgeon control and flexibility.

5.3. Indications for Use

The Alcon Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next Generation laser.

5.4. Brief Summary of Nonclinical Tests and Results

The device will comply with applicable sections of the following standards:

Standard #	**Title**
10993-1: 2003 AAMI / ANSI / ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing
10993-5: 1999 AAMI / ANSI / ISO	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity
10993-7: 1995 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals
10993-10:2002 AAMI / ANSI / ISO:	Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization
10993-11:1993 AAMI / ANSI / ISO	Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity
11135: 1994 AAMI/ISO	Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization
AAMI/ISO 11137:1994	Sterilization of Healthcare Products - Requirements for Validation and Routine Control - Radiation Sterilization
14971:2000 ISO	Medical Devices: Application of Risk Management to Medical Devices
60601-1: 2003 UL	Medical Electrical Equipment, Part 1 – General Requirements for Safety
60601-1:1988 IEC: A1:1991-11 + A2:1995 -03	Medical Electrical Equipment, Part 1 – General Requirements for Safety. (Including A1:1992, A2:1995 and A13:1995)
60601-1-2 :2001 IEC	Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility–Requirements and test.
60601-1-4:1996 IEC	Medical Electrical Equipment, Part 1: General Requirements for Safety. 4. Collateral standard: Programmable electrical medical systems. (Including A1: 1999)
60601-2-2: 1998 IEC	Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment
60601-2-18: 1996 IEC	Medical electrical equipment - Part 2: Particular requirements for the safety of endoscopic equipment
60601-2-22: 1995 IEC	Medical electrical equipment Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

The Alcon Vision System consumable products are provided sterile and intended for single use only. These products will be EtO or gamma sterilized and the process will be validated per the standards: AAMI/ISO 11135:1994: Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization or AAMI/ISO 11137:1994: Sterilization of Healthcare Products—Requirements for Validation and Routine Control—Radiation Sterilization.

Reusable handpieces are not provided sterile. Validated reprocessing instructions for cleaning, sterilization and re-use will be provided in the Directions for Use of the product.

Technological characteristics affecting clinical performance are similar to that of predicate devices previously listed. The Alcon Vision System will be developed and manufactured in compliance with FDA and ISO quality system requirements. Test data and documents were submitted that demonstrated the substantial equivalence of the IOP control features of the proposed and predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2008

Alcon Research, Ltd.
c/o Terry J. Dagnon
Senior Director, Regulatory Affairs
6201 South Freeway, R7-20
Fort Worth, TX 76134-2099

Re: K063583
Trade/Device Name: Alcon Vision System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: April 11, 2008
Received: April 14, 2008

Dear Mr. Dagnon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063583

Device Name: Alcon Vision System

Indications for Use:

The Alcon Vision System is an ophthalmic microsurgical system that is indicated for both anterior segment (i.e. phacoemulsification and removal of cataracts) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional Next Generation laser.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel L. Kaufman

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

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